Patent

Attorney Docket: 270/070

AI

however, and the "BMP-2 primers" used were potentially capable of amplifying both BMP-2 and BMP-4, which are highly homologous. Thus, this data alone cannot be definitively interpreted as showing amplification of BMP-2 in the absence of sequencing data. --

## **REMARKS**

Applicant submits that he has filed the above amendment in order to clarify the conclusions that could have been drawn from the RT-PCR data that was available at the time the application was filed and to comply with the duty of disclosure under 37 C.F.R. 1.56. Because the amendment simply clarifies rather than augments the data, it does not constitute new matter.

The RT-PCR products described on page 30 of the specification were obtained by performing RT-PCR on human lung tumor samples with primers that could potentially anneal with both the BMP-2 and BMP-4 genes, which encode two highly homologous proteins. At the time of filing of this patent application, these RT-PCR products had been analyzed by electrophoretic separation on an agarose gel, but the separated fragments had not been sequenced. Thus, the above amendments make clear that although the RT-PCR data from the agarose gel separation seemed to indicate that the BMP-2 gene had been amplified, especially when viewed in light of applicant's Western blot experiments, this was not the only possible conclusion that could have been drawn from the RT-PCR data. At the time of filing the application, one of skill in the art would have understood the need to perform sequencing before being able to definitively identify an RT-PCR product. Therefore, the amendments do not constitute new matter.

Subsequent sequencing of the RT-PCR products revealed amplification of BMP-4 rather than BMP-2. This later experiment and data have been described in a continuation in part application filed on May 2, 2002. Because applicant discloses this data in the continuation in part application, the above amendment was considered necessary to make clear that the RT-PCR products had not been sequenced at the time of filing of the parent application, and therefore could not have been definitively interpreted at that time. Thus, this amendment has been filed to fully comply with the duty of disclosure under 37 C.F.R. 1.56.

Patent

Attorney Docket: 270/070

If the Examiner has any questions regarding this preliminary amendment, he or she is invited to contact the undersigned at (213) 489-1600.

Respectfully submitted,

LYON & LYON LLP

Dated:  $\frac{6/25}{02}$ 

By:

Michael J. Wise Reg. No. 34,047

22249

PATENT TRADEMARK OFFICE

LYON & LYON LLP

633 W. Fifth Street, Suite 4700

Los Angeles, CA 90071

Tel: (213) 489-1600 Fax: (213) 955-0440

3